Master Protocol Trials: Facilitating accelerated and successful delivery of innovative designs

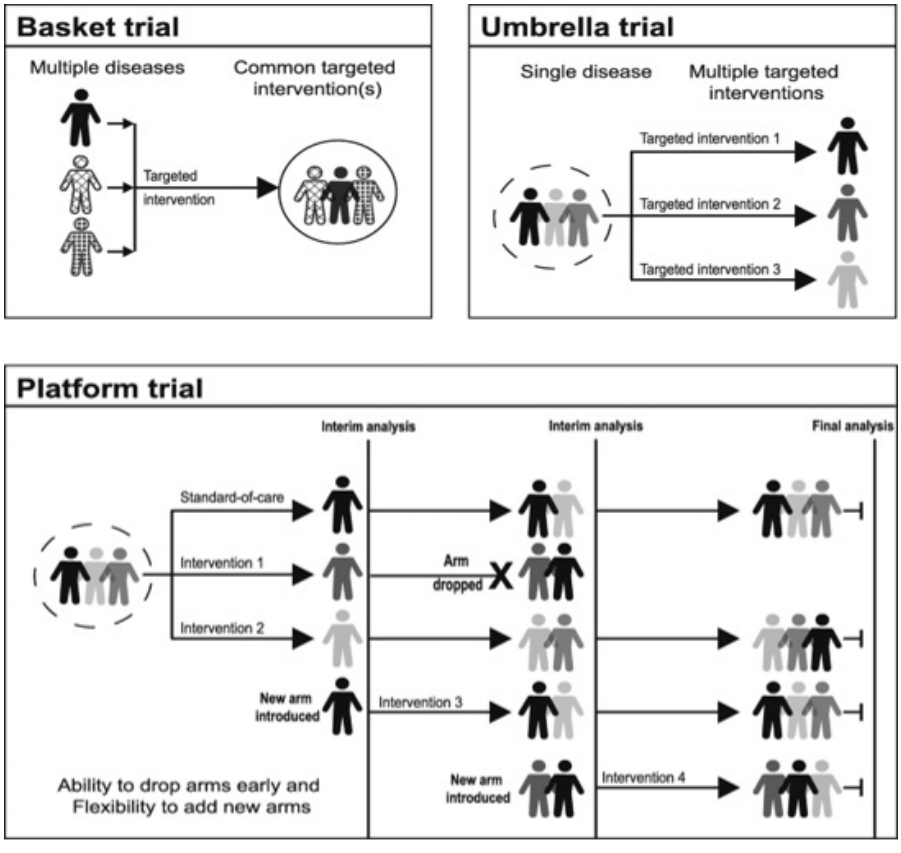
September 2021

parexel®

What change does Parexel see happening with adoption of master protocols in the clinical research community?

Master protocols were developed to more efficiently address the clinical development challenge of determining which therapy or combinations could get the most robust response in diseases that have the same overall clinical trial structure. Where using a master protocol is an option, whether that is a basket, umbrella, platform, matrix, or other design, we can help get the right treatments to the right patients faster through more rapid decision-making processes.

As a response to shortcomings of traditional study designs which have been accelerated by the COVID-19 pandemic, regulatory agencies and the research community alike have acknowledged the increased need for different ways of performing clinical trials. Our patient focus means we are striving to promptly deliver solutions that address unmet patient needs while maintaining high data quality and integrity.



Images from : Park, J.J.H., Siden, E., Zoratti, M.J. et al. Systematic review of basket trials, umbrella trials, and platform trials: a landscape analysis of master protocols. Trials 20, 572 (2019). https://doi.org/10.1186/s13063-019-3664-1

How do we address this change?

Whether we can contribute to the protocol development or help customers in determining the best development strategy, we already advocate the adoption of these new trial designs through our consultant strategy group. The statistical methodology is well developed but we believe that all study delivery team members from all functions need materials that help them understand and overcome the operational challenges to conduct these studies successfully.

With customer input and contributions from Parexel experts, we developed a playbook that project teams can use to facilitate the successful execution of master protocol trials. Critical input was collected that could potentially be involved in operationalizing a study.

What is the Parexel differentiator?

At Parexel, we strongly believe that the operational challenges of complex, innovative study designs are outweighed by their benefits, and we anticipate that this new approach to clinical drug development will soon become the new norm across all therapeutic areas.

We have a few differentiating factors that help set us apart from others in this space:

Experts in Parexel are brought together in our Complex Innovative Design (CID) expertise group. The group leads our set of solutions for addressing the new techniques used in clinical trials.

The CID maintains the Master Protocol Playbook which is supported by its network of experts across all functions, including Medical, Regulatory, Biostatistics, Project Leadership, Data Management, Clinical, Logistics, Medical Writing, and RWE.

We have strong and growing project teams experienced with designing and executing novel and adaptive study designs

Our teams are adept at making quick mid-trial decisions and modifications.

Parexel project teams and experts will be guided by the playbook but also able to recommend further enhancements which CID will regularly review and use to update and expand the playbook. This smart approach to knowledge management helps Parexel stay ahead with the practical implementation of cutting-edge study design innovation.

About the playbook

As part of our endeavor to be easy to work with, we are committed to constantly refining the way we deliver studies. This is done through investments and improvement of our systems, tools and processes to enable the evolution of clinical trial designs, and also through the provision of support to teams involved in complex innovative trials. While technology is a key component to the successful execution of complex innovative trials, practical, operational guidance is also essential to ensure our teams are trained and feel confident about conducting such trials.

The playbook looks at all areas of the traditional trial delivery process to provide guidance to project teams on how to overcome challenges and maximize the opportunities that characterize master protocols. The playbook describes how teams need to be structured and organized to address the concurrency of activities and the potential duration of the engagement. Team members or contingent team members need to be available to deal with the variability in workload that may occur. As well as team structure, project management and governance, we take a deep dive function-by-function approach in the playbook and look at how to best address challenges and attain potential benefits. We cover feasibility, regulatory submissions and approvals, site management and monitoring, data management, data availability, safety management, quality management, and all other components of successful delivery, at each step of the study lifecycle. We also provide suggestions as to how vendors can be best integrated into a project and also how this type of design may impact how Parexel as a service provider can best be contracted and managed to facilitate customer oversight and ease of doing business.

In conclusion

- Parexel is embracing the new drug development paradigm and actively implementing the shift from traditional clinical trial designs to new complex and innovative designs.
- The playbook is one part of our multi-faceted approach, directed by our clinical development leadership and enacted through multiple working groups and subject matter experts in Parexel to accelerate the delivery of new treatment options to patients.

With Heart™

We're always available for a conversation

Parexel International Corporation
275 Grove Street, Suite, 101C, Newton, MA 02466, USA
+1 617 454 9300

Offices across Europe, Asia, and the Americas
www.parexel.com

parexel®